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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

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24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/392,822	Applicant(s) YU ET AL.	
	Examiner Joseph Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,8,14-16,21,24-26 and 32-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,8,14-16,21,24-26 and 32-46 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

File

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 14, 2002, paper number 22, has been entered.

DETAILED ACTION

This application filed September 9, 2000, claims benefit to provision application filed September 10, 1999.

As indicated in the request for continued prosecution of the instant application, the after final amendment filed December 14, 2001, paper number 20, has been entered. The specification has been amended. Claims 1, 8, 14-16, 21, 24-26 have been amended. Claims 32-34 have been added. In addition, Applicants amendment filed March 4, 2002, paper number 23 has been received and entered. Claims 35-46 have been added. Claims 1, 8, 14-16, 21, 24, 25, 26 and 32-46 are pending and currently under examination.

Specification

The disclosure is objected to because of the following informalities:

The specification has been amended to exclude most reference to SEQ ID NO: 1 by deleting Figure 2 and references to said sequence in other parts of the specification. However, the Brief Description of the Drawings (page 9; lines 5-6) still refers figure 2. The brief description of the drawings should be amended to reflect the deletion of Figure 2, also renumbering the proceeding figures. Additionally, with the deletion of SEQ ID NO: 1, the sequence listing should be updated to delete reference to this SEQ ID NO.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 21 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The final Written Description Examination guidelines were published on January 5, 2001 (66 FR 1099) and are available at http://www.uspto.gov/web/menu/current.html#register.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar,* 19USPQ2d at 1116.

The instant claims are drawn to method or compositions comprising cell status-specific TREs and/or cell type-specific TREs. Additional claims recite embodiments wherein the cell status-specific TRE and/or the cell type-specific TRE comprises an additional element (e.g. HRE, element from E2F-1 gene, heat-inducible element, etc.) or wherein the cell status specific TRE comprises a cell status specific promoter or cell status specific enhancer. In none of the claims is it actually clear how to distinguish or determine what constitutes the metes and bounds of the terms cell status-specific TRE, cell type-specific TRE, cell status specific promoter or cell status specific enhancer. The definitions in the present disclosure are vague or circular in nature and do not provide an adequate written description for one of skill in the art with a given molecule of DNA to determine whether that molecule possesses regulatory elements in accordance with the recited terms. The "status" of cells is determined by the overall conditions or stimuli for growth that they are receiving. The terms "cell status-specific TRE" and "cell type specific TRE" do not provide a recognizable core structure identifying members of this genus. Moreover, it is not clear what is included or excluded from these terms inasmuch as they depend from an ever changing cell status *context* in which a regulatory element may or may not meet the definition set

forth. Gene regulation is extremely complex. A promoter that is responsive to stress conditions, such as heat, low O_2 or radiation is in fact responsive to a complex array of signal transduction events culminating in activation of an assortment of multiprotein complexes, comprising many standard transcription factors, such as AP-1, NF-κB, and CREB, or basal transcription factors such as TBP. Each of these factors has specificity for particular short stretches of sequence. Would the recognition elements for any one of the multiple factors involved in the activating, for example, the "hypoxia-inducible" egr-1 promoter be considered a cell status-specific element? Additionally, would a DNA sequence recognized by a transcription factor responsive to hypoxia (see e.g. p. S129 left column., Dachs *et al.*, Br. J. Cancer, 74(Suppl. XXVII):S126-S132, 1996) meet the limitations of a cell status-specific TRE? Claims 35 and 36 attempts to limit the claim by reciting the TRE comprises a cell cycle-specific element from the E2F-1 gene. However, it is not clear what part of the E2F-1 gene, or indeed what part of any of the claimed subject matter, actually constitutes a cell status-specific TRE.

While the specification and the art provides adequate written description for each of the specific sequences disclosed and defined in the instant specification, the specification fails to adequately describe other nucleic acid sequences which can clearly be distinguished as a TRE and/or HRE, or hybridize to said sequences. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying

characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, an adequate written description of a DNA or regulatory element therefrom requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA or regulatory element itself. It is not sufficient to define an element solely by its principal biological property, i.e. element that allows a cell status-specific TRE to function, *or by what it is not, i.e.* distinct from "cell type", which relates to a differentiation state, because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any DNAs carrying that specific regulatory element. Naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as a nucleic acid, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the nucleic acid has been isolated. Thus, claiming all DNAs that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. The specification teaches provides several specific sequences as set forth in SEQ ID NOs for the broad general guidance on how to use the large genus of sequences, however the specification fails to describe the relevant identifying characteristics of all the nucleic acid sequences which meet the functional limitations or which hybridize for use in the

instantly claimed methods. The skilled artisan cannot envision all the possible variant nucleic acid sequences which would hybridize but do not encode a *Der*HMW-map protein, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In the instant case, the specific sequences disclosed in the present disclosure do not provide adequate support the large genus of all the possible sequences encompassed for use in the instantly claimed methods.

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can

> do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Because Applicants have failed to provide an adequate written description of the materials used in the compositions and methods claimed and because there is no evidence that Applicants possessed any TRE embodiments beyond those disclosed and/or known in the prior art, the rejected claims fail to meet the written description requirement under 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 1, 8, 14-16, 21, 25, 26 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Claim amendments to encompass *in vitro* methods of propagation and recite particular elements of an adenovirus encompassed by the claims have obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 14-16, 21, 24, 26 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 15, 16, 21, 40 is indefinite in their recitation of the term "cell-type specific transcriptional regulatory element (TRE)" since the specification does not clearly define the phrase or its metes and bounds. The specification provides a circular definition of the term: "the term 'cell status-specific TRE' is one that allows a cell status-specific TRE to function" (page 12, lines 11-13) and attempts to qualify the definition by stating that the term applies to "a cell which exhibits a particular physiological condition, including, but not limited to, an aberrant physiological state" (lines 13-14) and a condition wherein "cell status...refers to a given, or particular, physiological state (or condition) of a cell, which is reversible and/or progressive...generated internally or externally" (lines 15-17). It is not clear what, if anything, is excluded from the definition as set forth thereof.

Claims 1, 8, 24, 26 and 40 are indefinite in their recitation of the term "hypoxia responsive element" or "HRE" since it is unclear how this term is defined or what its metes and bounds are. Apart from a HRE comprising SEQ ID NO:1, it is unclear what other elements are embraced by this term. For example, given a promoter-enhancer region responsive to hypoxic

conditions, it is unclear which specific element(s) thereof can be considered to be excluded from the definition of "hypoxia responsive" (*i.e.* specific enhancer binding sequence, TATA box etc.).

Claim 14 is indefinite in its recitation of the term "cell type-specific TRE" since the definition in the specification (*i.e.* page 18, lines 13-21) does not clearly define its metes and bounds. For example, the definition begins with a vague and relative definition describing an element that is "preferentially functional in a specific type of cell relative to other types of cells" (lines 13-14). Part of the vagueness is that gene expression is responsive to exogenous signals in a particular cell context; however, the claims do not provide any context or conditions for comparison. The description goes on to suggest that a "cell type-specific" TRE can be active in more than one cell type--an apparent misnomer. In attempting to explain the metes and bounds of embodiments embraced by this broader interpretation, the description provide a circular definition without sufficient clarity for one of skill in the art to determine its metes and bounds:

> "when a cell type-specific TRE is active in more than one cell type, its activity is restricted to a limited number of cell types, i.e. it is not active in all cell types" (lines 18-20).

Thus, it is not clear what is what metes and bounds apply to the term "cell type-specific TRE".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8, 14-16, 21, 25, 26 and 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Henderson *et al.* (WO 97/01358) Hallenbeck et al. (WO 96/17053), Walther *et al.* (Mol. Biotechnol., 6:267-286), Dachs *et al.* (Nat. Med., 3(5):515-520,), Dachs *et al.* (Oncol. Res., 9:313-325), Advani *et al.* (Semin. Oncol., 24(6):633-638), and Parr *et al.* (Nat. Med., 3(10):1145-1149).

Henderson *et al.* disclose conditionally replicative-competent adenoviruses designed to limit cytolytic replication to specific cell types due to operable linkage of a cell type-specific TRE to adenoviral genes essential for replication, and optionally carrying a heterologous gene product (see abstract and page 52, claim 21). Henderson *et al.* discloses a preferred embodiment comprising replication competent adenovirus comprising a prostate specific antigen (PSA) TRE comprising a cell status specific enhancer (nucleotides from 503 to 2086 of SEQ ID NO:3) and a cell status specific promoter (nucleotides from about 5285 to about 5836 of SEQ ID NO:3) operably linked to the adenovirus E1A promoter (i.e. CN706, p. 33-38; as evidenced by p. 49, lines 16-19 of the specification). Hallenbeck *et al.* discloses conditional replication competent adenoviruses to limit cytolytic replication to specific cell types due to operable linking an adenoviral early gene to any one of a number of different tissue or tumor-specific promoters (see abstract and claims 1 and 3). Hallenbeck *et al.* further teaches that the adenovirus vectors of the claimed invention can further comprise a heterologous gene product, such as one that is toxic for cells in the targeted tissue for use in a method of killing cells (page 23, lines 1-4 and claim 8). Walther *et al.* reviews the state of the art concerning targeted vectors for gene therapy of cancer and discloses several types of cell status-specific TREs including those comprising a hypoxia

responsive elements and heat-inducible elements (see e.g. "Tumor Therapy-Inducible Gene Therapy" section pages 279-281). Walther *et al.* teaches specific radiation-inducible and heat-inducible promoters comprising cell status-specific TREs which "serve as a source for suitable promoters to be exploited for expression regulation of therapeutic genes" (page 279), since radiotherapy and hypothermia, two well-established therapies of human cancers, induce a broad class of cell status-specific promoters that "provide a great potential for the construction of "therapy-inducible" vectors to express auxiliary therapeutic genes that might *act synergistically* with conventional therapies of human tumors" (emphasis added, from page 281). Walther *et al.* does not explicitly recite the term "cell status-specific TRE" nor does Walther *et al.* refer to hypoxia-inducible response (HRE) elements or cell cycle-specific elements. Dachs *et al.* (Nature Med.) disclose an experimental approach for targeting tumors wherein the hypoxic environment of a tumor can be exploited for activating heterologous gene expression driven by the hypoxia-response element (HRE) comprising a cell status-specific TRE contained in the mouse PGK-1 promoter. Dachs *et al.* teaches that use of HREs can be used to develop gene therapy against the drug- and radiation-resistant hypoxic population in tumors. Dachs *et al.* (Oncol. Res.) reviews the state of the art concerning targeted vectors for gene therapy of cancer and provides a detailed account essentially supporting the use of cell status-specific TREs (page 314). More specifically, Dachs *et al.* discloses several types of cell status-specific- and cell type-specific TREs including those comprising hypoxia responsive- and radiation-responsive TRE elements (in "Condition-Targeted Expression" section, page 318-319). Dachs *et al.* teaches that "severe hypoxia is also a physiological condition specific to tumors, which makes it a potentially

exploitable target...[such that they]...have utilized hypoxia response elements (HRE) derived from the oxygen-regulated phosphoglycerate kinase gene to control gene expression in human tumor cells in vitro and in experimental tumors" (abstract, page 313) and that the abnormal hypoxic conditions characterizing almost all solid tumors is "a major hindrance to therapy", since "cells in this aberrant environment can remain viable and are often chemo- and radioresistant" (page 318). Dachs *et al.* further reviews several studies targeting transgene expression to tumorous or ischemic tissues, wherein transgene expression is selectively induced on account of their operable linkage to HRE elements responsive to the hypoxic environment of the diseased tissues. Additionally, Dachs *et al.* describes the benefits of adenoviral delivery of a Egr-1-controlled TNF-α construct in conjunction with radiation which was shown to result in extensive intratumoral vascular thrombosis and necrosis, whereas no thrombosis was detected in treated normal tissue. Advani *et al.* discloses the benefits of employing cell status-specific TREs comprised of radiation-inducible promoters and teaches that "[i]ncreasing local tumor control by combining radiotherapy and gene therapy may improve the outcome of cancer treatments by decreasing tumor mass more effectively while limiting systemic toxicity. Parr *et al.* discloses adenoviral vectors comprising transgenes operably linked to a E2F-1 promoter containing a cell status-specific TRE that can mediate tumor-selective gene expression in vivo, allowing for eradication of established gliomas with significantly less normal tissue toxicity than seen with standard adenoviral vectors (abstract). Parr *et al.* further point out that since many tumors contain mutations that affect the Rb/E2F pathway, and since de-repression of the E2F-1 promoter occurs in cancer cells in vivo, viral vectors incorporating E2F-responsive promoters

can be exploited to design viral vectors that mediate tumor-selective gene expression" (abstract and page 1147, right column).

In summary, Henderson and Hallenbeck teach adenovirus vectors which comprise cell specific TREs. Specific TRE sequences are disclosed and used by Henderson and Hallenbeck, and shown to be effective in the particular cell types tested, however they do not provide other specific TRE sequences or methods and context of use for other cells and conditions. At the time the invention was made it would have been *prima facie* obvious to one of ordinary skill in the art to substitute or combine methods the cell type specific TREs in the conditionally replication-competent adenovirus vectors of Henderson and Hallenbeck with the cell status-specific TREs disclosed by Walther, Dachs, Advani, or Parr, since each Walther, Dachs, and Advani teach the benefits of combining tumor specific, cell type specific, and/or cell status-specific regulatory elements. One would have been motivated to substitute other specific promoters since the art teaches and supports the use of cell status specific regulatory elements are inducible by well-established treatments, e.g. radiation and hypothermia. Further, Walther, Dachs, and Parr teach that operably linking radiation-inducible, heat-inducible, hypoxia-inducible or cell cycle-inducible regulatory elements (comprising cell status-specific TREs) allows for more effective and selective transgene expression and tumor eradication with significantly less normal tissue toxicity than seen with standard adenoviral vectors. Additionally, substituting and/or combining the cell type-specific regulatory elements of Hallenbeck and Gregory with the cell status-specific TREs of Walther, Dachs, Advani, or Parr would have been in accordance with the goals and teachings of Hallenbeck and Gregory. There would have been a reasonable expectation of

success to simply substitute the various promoters taught by Walther, Dachs, Advani, or Parr into the adenovirus constructs of Henderson and Hallenbeck in view of the working examples provided in each of the references which teach the use of the embodiments can be predicted with a high expectation of success.

Thus, absent evidence to the contrary, the invention was *prima facie* obvious at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-16 and 21 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 8, and 32 of copending Application No. 09/151,376. Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejected claims fully embrace claims 1-4, 8, and 32 of the co-pending application

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Joe Woitach

AU 1632